### IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: OHIO EXECUTION PROTOCOL LITIGATION

Case No. 2:11-cv-1016

This document relates to: PLAINTIFF CLEVELAND JACKSON CHIEF JUDGE EDMUND A. SARGUS, JR. Magistrate Judge Michael R. Merz

Expert Report of Dr. David J. Greenblatt, M.D.

- I, David J. Greenblatt, under the penalty of perjury, declare the following to be true:
  - 1. My name is David J. Greenblatt, M.D. I am the Louis Lasagna
    Endowed Professor in the Department of Immunology (formerly the
    Department of Pharmacology and Experimental Therapeutics) at Tufts
    University School of Medicine in Boston, Massachusetts. I am also a
    Professor of Psychiatry, Medicine, and Anesthesia at Tufts University
    School of Medicine. I am also appointed to the Special and Scientific
    Staff (Research) at Tufts Medical Center in Boston, Massachusetts. I
    am a Board-certified clinical pharmacologist, a professor, and an
    investigator in basic and clinical pharmacology. The factual

- statements I make in this declaration are true and correct to the best of my knowledge and experience.
- 2. I have been asked by counsel representing inmate Cleveland Jackson to provide opinions related to the lethal injection execution protocol employed by the State of Ohio and the alternative lethal injection execution protocols that Mr. Jackson has alleged in his motion for preliminary injunction and stay of execution.
- 3. I previously provided an expert report (ECF No. 1956), an amended expert report (ECF No. 1976-3), an expert rebuttal report (ECF No. 2003), and hearing testimony (ECF No. 2113, PageID 104162–263) in the above-captioned case on behalf of Plaintiff Warren K. Henness. I stand behind the opinions expressed in those reports and my testimony, and adopt them and incorporate those reports and testimony here in full for the purposes of this report as well.
- 4. In preparing this updated report and reaching the expert opinions contained herein, I again incorporate the materials I previously reviewed for my previous reports, and I have also reviewed, among other materials, the following:
  - 1) The Brief of State Appellees, *Henness v. DeWine*, 6th Circuit Case No. 19-3064, Doc. No. 33
  - 2) Decision and Order On Motion for Stay of Execution and Preliminary Injunction, ECF No. 2133

- 3) Plaintiff Jackson's Second Amended Individual Supplemental Complaint, ECF No. 2227
- 4) Plaintiff Jackson's Amended Motion for Stay of Execution, Preliminary Injunction, and Evidentiary Hearing, ECF No. 2242
- 5) Autopsy report from autopsy of Donnie Johnson, executed by the State of Tennessee on May 16, 2019
- 6) Autopsy report from autopsy of Dominique Ray, executed by the State of Alabama on February 7, 2019
- 7) A compilation of documents entitled Articles Describing Midazolam Executions (2019)
- 8) A video of a press conference following the Donnie Johnson execution at which witnesses recounted their observations, available at <a href="https://www.facebook.com/newschannel5/videos/tennessee-execution/297932371149654/">https://www.facebook.com/newschannel5/videos/tennessee-execution/297932371149654/</a>
- 9) A certified transcript of the Johnson press conference
- 10) Lethal Injection Chemical Administration Record and Chemical Preparation Time Sheet for Johnson execution
- 11) Lethal Injection Chemical Administration Record and Chemical Preparation Time Sheet for Irick execution
- 12) Bloomfield SS, Tetreault L, Lareniere B, Bordeleau JM., A method for the evaluation of hypnotic agents in man. The comparative hypnotic effects of secobarbital, methaqualone and placebo in normal subjects and in psychiatric patients, J Pharmacol Exp Ther. 1967;156(2): 375-382
- 13) Dobos JK, Phillips J, Covo GA. Acute barbiturate intoxication. JAMA. 1961;176:268-272
- 14) Epstein LC, Lasagna L., A comparison of the effects of orally administered barbiturate salts and barbiturate acids on human psychomotor performance. J Pharmacol Exp Ther. 1968;164(2): 433-441
- 15) Glare PA, Walsh TD. Clinical pharmacokinetics of morphine. Ther Drug Monit. 1991;13(1):1-23

- 16) Greenblatt DJ, Allen MD, Harmatz JS, Noel BJ, Shader RI. Overdosage with pentobarbital and secobarbital: assessment of factors related to outcome. J Clin Pharmacol. 1979;19(11-12):758-768
- 17) Hadden J, Johnson K, Smith S, Price L, Giardina E. Acute barbiturate intoxication. Concepts of management. JAMA. 1969;209(6):893-900
- 18) Mattu A, Martinez JP, Kelly BS, Modern management of cardiogenic pulmonary edema, Emerg Med Clin North Am. 2005;23(4):1105-1125
- 19) Perina DG., Noncardiogenic pulmonary edema, Emerg Med Clin North Am. 2003;21(2):385-393
- 20) Urbach KF., Hypnotic properties of amitriptyline: comparison with secobarbital, Anesth Analg. 1967;46(6):835-842
- 21) Any other source cited in this report.

### **BACKGROUND AND EXPERT QUALIFICATIONS**

- 5. My professional qualifications are fully expressed in my curriculum vitae appended to this report. Brief highlights include those mentioned in my previous expert reports submitted in this case, incorporated here as well.
- 6. Additional, more recent highlights include the following.
- 7. I have been teaching and doing research in basic and clinical pharmacology since beginning prior to completing my residency after graduating from Harvard Medical School in 1970, and ongoing to the present.

- 8. I have been employed in a variety of positions at Tufts University
  School of Medicine in Boston, Massachusetts, and its affiliated
  hospital, Tufts Medical Center, since 1979. During that time, I have
  been a professor at the medical school in several departments,
  including Psychiatry, Medicine, and Anesthesia, as well as the
  Department of Pharmacology and Experimental Therapeutics (now the
  Department of Immunology). I have held academic appointments as a
  faculty member, teaching and doing collaborative research within
  those departments. I am also Board-certified in Clinical
  Pharmacology.
- 9. In my current position, I remain the Louis Lasagna Endowed Professor at the Tufts University School of Medicine. The late Dr. Louis Lasagna is considered the father of clinical pharmacology, and the medical school holds an endowment in his name. It is significant credential within academia to have been named the professor receiving that endowment.
- 10. Over the course of my career, I have been recognized with numerous awards and honors, as listed in my previous report.
- 11. My current work continues to be a combination of research, teaching, and training. My research involves both clinical research on human volunteers, and the fundamental scientific research on molecular pharmacology and the function of drug-metabolizing enzymes. I also

train graduate students who are pursuing a Ph.D. or master of science in pharmacology and experimental therapeutics. I also teach students in the medical school who are planning to become physicians, or students pursuing a Master of Science degree in biomedical science, which involves traditional classroom teaching as well as one-on-one instruction.

12. In addition to these professional responsibilities, I also carry administrative responsibilities as well. I also serve on the editorial board of a number of peer-reviewed journals. I am the editor-in-chief of two such journals. The first is the Journal of Clinical Psychopharmacology, which is also edited by Dr. Richard I. Shader, one of my colleagues. The second journal is called Clinical Pharmacology in Drug Development. I am the sole editor-in-chief of that journal. In addition, I serve on the Editorial Boards of several other peer-reviewed journals, including: Journal of Clinical Pharmacology; Biopharmaceutics and Drug Disposition; Xenobiotica; Neuropsychopharmacology (1986-1990); Drug Investigation; Drugs and Aging; Pharmacology and Toxicology; and Drugs and Therapy Perspectives. At Tufts University, I am Director of Admissions for the Graduate Program in Pharmacology and Drug Development. I serve on the Medical School Admissions Committee, the Radiation Safety Committee, and the Basic Science Appointments, Tenure, and Promotions Committee.

- 13. Peer-reviewed scientific journals require rigorous review of proposed research studies, papers, or reports, conducted by multiple, anonymous reviewers. Those submitted manuscripts would be sent back to the authors with commentary about the needs for revision, after which the works are resubmitted. This review sets a high bar for scientific research before it is published.
- 14. Over the course of my career, I have had approximately 800 original research articles subjected to the peer-review process and published. The first of those was published in 1967, while I was still in medical school. I continue to publish original research articles to this day. I have published at least three additional original research articles since my initial report submitted in this case in October of 2018, bringing my current total to 786 articles.
- 15. In addition, I have had more than 100 Editorials and Responses to published works that were, themselves, published, including at least four such additional publications since my October 2018 report in this case. I have also published approximately 174 Book Chapters and Reviews, most of which were also peer-reviewed, including one such additional publication since my October 2018 report in this case. I have also authored, solo or with co-authors, at least 12 books.
- 16. Google Scholar is a method of analysis of publications and how frequently they are cited by other scholarly works. Google Scholar

uses the information in the National Library of Medicine run by the National Institutes of Health, which also runs an indexing service called PubMed. That data is then turned into what is called a Google Scholar Citations Index score, which means the number of citations in other published scholarship to works that the individual has authored or co-authored.

- 17. In my field, the Google Scholar Citations Index for any particular citation is relied upon to identify key articles or other works. By extension, if a scientist has developed a Google Scholar Citations Index public profile (a very easy and free task), the scientist's scores can also serve as a helpful proxy for the level of a scholar's expertise, experience, credibility, and influence within one's field. In my October 2018 report in this case, my Google Scholar Citations Index was 65,726. As of the date of this new report, my Google Scholar Citations Index was 67,339.
- 18. The h-index is another way of assessing citations through Google Scholar. An "h" number is the largest number h such that h publications have at least h citations. So, for instance, an h-index of 50 means that a scholar has 50 papers, each of which has been cited at least 50 times. At the time of my October 2018 report, my h-index score was 119. It has now increased to 120. According to a recent analysis of the most highly cited researchers using data collected in

the first week of October, 2018, my h-index score (which was 118 at that time) placed me among the top 1600 most-cited scientists worldwide for all scientific disciplines, over all time.<sup>1</sup> In the 10th edition of that analysis, released in April of 2019 when I had an h-index score of 119 and a total number of citations of 66,139, I am now ranked among the top 1300 most-cited scientists worldwide for all scientific disciplines, over all time.<sup>2</sup>

- 19. An i10-index is a third way of assessing citations through Google Scholar. An "i10" number is the number of publications with at least 10 citations. At the time of my October 2018 report, my i10-index score was 837. It has now increased to 860.
- 20. Among my peer-reviewed, published research are at least two articles that are considered by the major indexing services to be "Citation Classic" publications, which means they have been cited more than 1000 times in other publications. One of those Citation Classic publications was a research review published in 1985 entitled "Midazolam: pharmacology and uses," which was published in

<sup>&</sup>lt;sup>1</sup> See 3160 Highly Cited Researchers (h>100) according to their Google Scholar Citations public profiles (9th ed.).

<sup>&</sup>lt;sup>2</sup> See Highly Cited Researchers (h>100) according to their Google Scholar Citations public profiles (10th ed.), http://www.webometrics.info/en/hlargerthan100.

"Anesthesiology," the major journal in the field of anesthesiology. In that article, my co-authors and I reviewed all the research done on midazolam up to that time, to synthesize that research into an understanding of the pharmacology and uses of midazolam. That article has been cited in other publications at least 1,082 times, and it continues to be cited regularly today. The other Citation Classic of which I am a co-author is entitled "A method for estimating the probability of adverse drug reactions," published in 1981 in "Clinical Pharmacology & Therapeutics." That article has now been cited at least 8,283 times, and it continues to be cited regularly today.

21. A great deal of my work in basic and clinical pharmacology has focused on the benzodiazepine class of drugs. As part of that research, I have worked extensively with midazolam. I first became involved with studying midazolam in the early 1980's, when my colleagues and I developed a method for measuring the drug in human and other animal plasma. We did a number of additional clinical studies of the drug, involving studies with human volunteers and patients, before the drug was even released for general clinical use. We conducted clinical studies of factors influencing how the drug is metabolized and cleared and distributed by the body. We looked at factors such as the effect of age on the drug's effects and metabolism, as well as gender, obesity, disease states, drug interactions with other drugs such as antibiotics and drugs being

- developed to treat HIV, as well as interactions caused by various foods and beverages.
- 22. In fact, a number of our studies of midazolam went into the original New Drug Application that submitted for FDA approval of midazolam. Since that time, I have continued to do extensive research on midazolam, including experimental research using models such as enzyme models and molecular models, as well as animal studies. I also continue to conduct clinical studies of the drug as well. For example, my colleagues and I have done a number of studies looking at the effects of midazolam on the electroencephalogram (EEG), which measure electrical brainwaves, and how those effects relate to their concentrations in plasma and to the dose administered.
- 23. A number of my research studies are pharmacokinetic/
  pharmacodynamics studies, because we looked at the connection
  between midazolam's effect on the body, which is pharmacodynamics,
  and the body's effect on the drug, how the body clears and removes
  the drug, which is called pharmacokinetics.
- 24. Clinical pharmacology is considered to be a branch of internal medicine. The principal focus of clinical pharmacology is on drug effects in humans, what their mechanisms of actions are (including pharmacodynamics), what their proper therapeutic uses are, what

- adverse reactions might occur, the patterns of use of a drug, and what kind of factors influence the effects of the drug.
- 25. Clinical pharmacology also subsumes many areas of basic pharmacology, particularly those that are directly relevant to understanding drug metabolism, pharmacokinetics, and clinical effects. That would include pharmacogenetics, which is how genetic factors influence drug effects, the molecular mechanisms of drug metabolism, and how the enzymes in the liver and elsewhere in the body transform drugs to be eliminated. Clinical pharmacology also involves other fields of study, including toxicology. Toxicology is the study of drugs given in excessive amounts and overdosage, and it incorporates the interpretation of plasma concentrations of drugs. I have experience in these fields though my work with basic and clinical pharmacology. That has given me an extensive understanding of the effects on the human body of excessive amounts and overdosages of drugs administered in different ways. Likewise, although I am not an anesthesiologist by training, I am a professor of anesthesiology and have an understanding of why certain drugs are used for procedures in the anesthesia context (and the limitations of those drugs), based on my work with basic and clinical pharmacology, including my extensive knowledge and understanding of the actions of those drugs. That experience also provides me an extensive understanding of the effects on the human body of barbiturates like secobarbital,

- benzodiazepines like diazepam and midazolam, opiate analgesics like morphine sulfate, cardiac glycosides like digoxin, beta-adrenergic antagonists like propranolol, and antidepressants like amitriptyline.
- 26. I have provided trial or deposition testimony as an expert witness in in-court expert witness testimony in 18 cases in the last four years, which are listed in my attached CV.
- 27. I am being compensated at the rate of \$300 per hour for research, evidence collection, document review, consultation, report-writing and travel related to this case. The maximum reimbursement per day out of the office is \$3000.

### SCIENTIFIC BASES AND OPINIONS REGARDING MIDAZOLAM AND OHIO'S THREE-DRUG LETHAL INJECTION PROTOCOL

- 28. I stand behind, and fully adopt here, the opinions expressed on this topic in my previous expert reports and testimony given in this case.
  (See Greenblatt Expert Report, ECF No. 1956; Greenblatt Amended Expert Report, ECF No. 1976-3; Greenblatt Expert Rebuttal Report, ECF No. 2003; Greenblatt Testimony, ECF No. 2113, PageID 104162–263.)
- 29. I also agree with the testimony of Dr. Edgar that the Court heard previously regarding the development of acute pulmonary edema in inmates executed with a protocol that includes an IV injection of 500 mg or more of midazolam. I also agree with Dr. Edgar's testimony

- about the cause of that acute pulmonary edema—namely, the large volume of acid injected into a vein. I discussed this subject in my previous reports, and I reiterate it here because I remain of the opinion that it is correct.
- 30. I also still agree with the testimony offered by other highly accomplished scientists in this case, such as Dr. Stevens, Dr. Lubarsky, Dr. Sinha, Dr. Bergese, and Dr. Exline, that midazolam does not protect a condemned inmate from the full scope of the severe pain and suffering associated with the second and third drugs in Ohio's current protocol. Their consistent testimony, grounded solidly in a correct understanding of the science, reconfirms that there is a scientific consensus regarding midazolam's pharmacology, pharmacokinetics, and its utter inability, at any dose, to become a pain-blocking drug.
- 31. I also agree with this Court's conclusion that midazolam at any dosage has no analgesic properties. (ECF No. 2133, PageID 105249.)

  Likewise, I agree with this Court's conclusion that because midazolam has no analgesic properties, it cannot prevent the pain incident to the second and third drugs from reaching the brain of the condemned inmate. (*Id.*) Further, I agree with this Court's conclusion that the second and third drugs in Ohio's protocol are so severely painful as to mandate that the State must do something first to prevent the inmate

from suffering that severe pain. (*Id.*) I also agree with the Court's conclusion that pulmonary edema that follows IV injection of high doses of midazolam in executions will certainly or very likely cause severe pain and needless suffering to the condemned inmate. (*Id.* at PageID 105250.) I also agree with the Court's assessment of the scientific method and how genuine science is conducted. (*Id.* at PageID 105252.)

- 32. I also highlight my agreement with the Court's conclusion that "it is certain or very likely that a 500 mg IV-injected dose of midazolam cannot reduce consciousness to the level at which a condemned inmate will not experience the severe pain" associated with the three drugs in Ohio's current protocol. (*Id.* at PageID 105253.) Because midazolam cannot suppress consciousness to the level required to be insensate to pain, and because midazolam cannot act on pain receptors like an opioid analgesic drug, there is, consequently, no way, as a matter of science, for midazolam to protect the inmate from being exposed to and experiencing the full measure of severe pain and suffering.
- 33. It is my understanding that the lethal injection protocol Ohio intends to use to execute Cleveland Jackson involves the same sequence of drugs it intends to use to execute Warren K. Henness: a sequence of three drugs injected intravenously, starting with 500 mg of

midazolam, then a paralytic drug called rocuronium bromide, and then potassium chloride.

34. I understand that additional executions using a three-drug midazolam lethal injection protocol have been conducted since my previous expert reports and testimony in this case. Based on the same scientific principles and testimony I provided before, principally the hard scientific fact that midazolam can never be a pain-blocking drug, at any dose, it is my expert opinion, to a reasonable degree of medical certainty, that Dominique Ray, Michael Samra, Christopher Price, and Donnie Johnson each surely or very likely remained sensate and experienced the full measure of severe pain and horrific suffering during their respective executions using three-drug midazolam lethal injection protocols. Each of them surely or very likely suffered the severe pain from developing non-cardiogenic acute pulmonary edema quickly after IV injection of 500 mg of midazolam, along with the burning pain from injection of that drug, as well as the severe pain and suffering associated with suffocation from the paralytic drug and the searing pain of injection of potassium chloride.

#### I. Midazolam's Characteristics

35. I stand behind, and fully adopt here, the opinions expressed on this topic in my previous expert reports and testimony given in this case.

(See Greenblatt Expert Report, ECF No. 1956; Greenblatt Amended

- Expert Report, ECF No. 1976-3; Greenblatt Expert Rebuttal Report, ECF No. 2003; Greenblatt Testimony, ECF No. 2113, PageID 104162–263.)
- 36. The pharmacology and pharmacokinetics of benzodiazepines remains the same from my previous reports. Thus, I adopt those previous opinions and explanations provided in those previous reports. I also reiterate the following opinions expressed in my previous report, to reemphasize them here.
- 37. Midazolam has no analgesic (pain-blocking) capabilities. By itself, midazolam cannot render a person insensate to pain, for two fundamental reasons.
- 38. First, midazolam cannot render someone insensate to pain because it is not an analgesic drug, at any dose. It does not have the chemical properties such that it can act on pain receptors. It acts on the benzodiazepine receptors, not pain receptors like opioids do. Thus, in circumstances such as a colonoscopy there is almost always some other drug administered along with the midazolam, such as an opioid analgesic. The analgesic drug protects against the person feeling pain, while the midazolam prevents traumatic memories from being formed and relaxes the person, making them drowsy enough to accept the procedure.

39. Second, midazolam cannot render someone insensate to pain because it does not have the ability to so deeply sedate someone to the level of unconsciousness at which there is an associated occurrence of insensation such that a person will fail to be aroused by noxious stimuli such as those caused by the drugs in Ohio's execution protocol. The nature of the drug's effect on the brain dictates this; no matter what dose is given, midazolam can only produce a degree of sedation that is insufficient to render a person insensate. This is because benzodiazepines act only on the frequency of the opening of the receptor chloride channel, as explained in my previous reports in this case, and as explained previously in this case at length by Dr. Stevens. That science remains unchanged. Unlike a barbiturate or a general anesthetic drug, which act on the duration of the chloride channel opening itself, midazolam only affects how frequently the channel opens. Thus, the drug will always permit less chloride into the channel than the drugs that keep the channel open for extended periods of time. Those limitations mean that, as a matter of scientific certainty, midazolam simply cannot make a person insensate by way of suppressing consciousness to a deep enough level. Only at a stage of sedation beyond what midazolam can legitimately achieve is there sufficient consciousness suppression to assure insensation. Midazolam simply cannot produce that level of unconsciousness.

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- 40. It still remains the case that the inmate subjected to Ohio's execution protocol must be made insensate first. Otherwise, he will be sure or very likely to experience the severe pain and suffering caused by the three drugs in the three-drug midazolam protocol. He will remain sensate if Ohio does not use an analgesic drug in its protocol; Ohio does not. He will also remain sensate if Ohio does not suppress his consciousness so deeply to the level at which unconsciousness and insensation occur together. But midazolam cannot achieve that level of unconsciousness, so he will not be insensate in that way either.
- 41. In my expert opinion, based on my background as a clinical pharmacologist researching the basic and clinical pharmacologic properties of midazolam, and as a physician trained in internal medicine, 500 milligrams of midazolam would not make the inmate insensate to protect him from the severe pain and suffering caused by Ohio's execution protocol, including: from the drowning and suffocating sensations of rapidly developing acute pulmonary edema; from the burning sensations of injection of that amount of acidic midazolam; from the burning sensations of injection of the acidic paralytic drug; from the suffocating effects of the paralytic drug; or from the severe burning upon rapid injection of a large dose of potassium chloride. In other words, it is sure or very likely that the inmate subjected to Ohio's three-drug midazolam lethal injection protocol will be subjected to one or more of those different types of

- severe pain and suffering associated with the drugs as used in Ohio's protocol.
- 42. I base that expert opinion on my own extensive background experience researching midazolam, as well as the general scientific consensus about the underlying mechanism of action of midazolam and other benzodiazepines, as reflected in the literature. It has no analgesic properties and cannot produce a sufficient level of sedation at which unconsciousness and insensation occur together to protect against noxious stimuli like the injection of the drugs in Ohio's protocol or the effects of those drugs. The midazolam simply does not do that.
- 43. That expert conclusion and general scientific consensus does not change even though Ohio plans to inject 500 mg or more of midazolam. I know of no research studies on the effect of a 500 mg or larger dose of midazolam. Such studies are unnecessary for us to know with sufficient certainty what such large doses of midazolam will do (and not do). First, because I can say with a high degree of scientific certainty that all relevant benzodiazepine receptors will be occupied at a dose of approximately 250 mg. Existing studies demonstrate there is a point in the range of 15-40 mg at which there is no further sedative effect created by additional doses of midazolam. And second, because there is data on what very large doses of other

benzodiazepines will do. Because the properties of individual drugs within this class are very similar, we can draw scientifically valid conclusions about the effects of 500 mg or more of midazolam from studies on overdosage of other benzodiazepines.

44. For example, I have been personally involved in conducting studies involving patients who were hospitalized because of benzodiazepine overdosage. (See, e.g., Greenblatt, DJ, et al., Acute overdosage with benzodiazepine derivatives, Clinical Pharmacology and Therapeutics, Vol. 21, No. 4, pp. 497-514, Apr. 1977; Divoll, M., et al., Benzodiazepine Overdosage: Plasma Concentrations and Clinical Outcome, Psychopharmacology (1981) 73:381-383; Divoll, et al., Pharmacokinetic Study of Lorazepam Overdosage, Am J Psychiatry 137:11, November, 1980; Greenblatt, D.J., et al., Rapid Recovery From Massive Diazepam Overdose, Journal of American Medical Association, Oct. 20, 1978, Vol. 240, No. 17.) We studied their clinical course and obtained blood or plasma concentrations as the persons came into the medical facility, and then for a period of time after that. We followed how they progressed and recovered and what their initial blood levels were, and how they declined with time. In one study, there were doses as large as 2 grams of diazepam, compared to the usual therapeutic dose of 10 mg. That equates to approximately 2000 mg of midazolam. Another person took a dose of

- between 450 and 500 mg of diazepam, which is many times the therapeutic dose of that drug.
- 45. The findings from those studies are all consistent. The studies each included the Lawson Mitchell sedation scale, which grades sedation and Central Nervous System (CNS) depression on a scale of 1 to 4. Levels 1 and 2 involved patients that remained more alert, with only slight levels of sedation, while the more serious levels of sedation were Levels 3 and 4. But in these studies, overdoses of benzodiazepines alone seldom if ever got to a sedation level of 3 or 4. Those that reached a Level 3 or 4 had taken other drugs in addition to the diazepam. With extremely large doses of benzodiazepines alone, the patients were sleepy and sedated, but they remained sensate, and they did not have problems with their breathing or respirations. After a day or so, they typically woke up and went home. When the patients mixed benzodiazepines with other drugs, the situation became more problematic, but those other drugs did not involve a paralytic or potassium chloride.
- 46. Other studies also support the conclusions that other experts in this case have drawn, including that one of midazolam's characteristics is that it has a maximum sedative effect that will prevent it from sedating the inmate to the point at which he will be deeply enough unconscious as to possibly be insensate.

- 47. For example, studies conducted by Bührer and Stanski (attached to this Report) used the EEG as an objective window on the brain to measure the depth of sedation. Dr. Stanski was a colleague of mine at Mass General before he went to Stanford, and I mentored him in his research training. My group collaborated with Bührer and Stanski on those studies, because they sent some of their blood samples to our lab to be analyzed.
- Bührer and Stanski reached two principal findings in their studies. 48. First, they demonstrated that when there is an increase in dose of midazolam beyond a certain level, there will not be an associated or parallel increase in the depth of sedation. When they went from 7.5 mg to 15 mg, there was a measurable increase in sedation on the EEG. But when they increased from 15 mg to 25 mg, there was no further increase in sedation. That is strong scientific proof that the maximum sedative effect of midazolam occurs somewhere in that 25-40 mg dosage range. The second principal finding from those studies was that midazolam has a delay in onset of maximum sedative effect, also called the peak effect. The time of maximum or peak sedative effect is the time at which the maximum effect will occur. Those studies showed that there was an average delay in onset of up to 20 minutes, or possibly more, to reach whatever midazolam's maximum effect level is.

- 49. Other studies that my colleagues and I conducted were of a generally similar nature to the Bührer and Stanski studies, using EEG measurements. (*See, e.g.*, Greenblatt, D.J., et al., Kinetics and EEG Effects of Midazolam during and after 1-Minute, 1-Hour, and 3-Hour Intravenous Infusions, Journal of Clinical Pharmacology, 2004;44-605-611; Greenblatt, D.J., et al., Pharmacokinetic and electroencephalographic study of intravenous diazepam, midazolam, and placebo, Clin. Pharmacol. Ther. 1989;45:356-65.) Those studies showed the same kind of result—a concentration at which there is no greater sedative effect achieved, as well as a delay in onset of maximum sedative effect.
- 50. The Bührer and Stanski studies also showed that as the size of the dose of midazolam increased, the time to peak sedative effect also increased. The higher the dose, the greater the delay. The reason for that can be found in the formulation of the drug and its intravenous preparation, which is formulated in acid to keep it in solution. Recall that midazolam is a benzodiazepine with an accessory ring called an imidazole ring. When the drug is in acid, the ring is open. And the drug actually undergoes a conformational change of its structure when the ring is open. The ring-open form is pharmacologically inactive. The drug solution must be buffered by the blood back to the normal pH 7.4 for that ring to close and for the drug to become active and be able to reach and affect the brain. Injecting smaller doses as

customarily used in clinical practice, contained in 1 or 2 ml of injection solution, allows the solution to be buffered more rapidly, thereby leading to a shorter time to peak effect. But injecting larger doses causes a delay in reaching peak effect, because the blood must buffer a larger amount of acid. It would take several circulations for that amount of acid to be buffered to pH 7.4. Each circulation would take approximately 60 seconds. I must also distinguish between "onset" (the first attainment of *any* sedative effect) versus time of maximum effect. The initial onset of *any* observable sedative effects may be a minute or more, but that is not the peak effect.

51. I should also note that the results of my study *Kinetics and EEG Effects of Midazolam*, as shown in Figure 4 of that article, might appear to support a linear relationship between the dose of midazolam and the effect on EEG. That, in turn, might be misconstrued to support the notion that if a dose of midazolam is increased beyond standard therapeutic doses, deeper levels of sedation could be achieved accordingly. That would be a misinterpretation of the study, however. We did not study different doses, we only studied one dose, which was .1 mg per kg of body weight. Additionally, the data makes clear that even with increases in plasma concentration, the EEG effect did not increase.

- 52. In my 1989 study, a 9 mg dose did not reach peak sedative effect for 15 minutes. The 500 mg dose of midazolam that Ohio intends to inject is approximately 50 times larger than the 9 mg dose for which peak sedative effect took 15 minutes.
- 53. Having reviewed the execution timeline logs produced by the State of Ohio during its executions of Ronald Phillips, Gary Otte, and Robert Van Hook, it appears that the State is injecting the 100 ml (500 mg) of midazolam rather quickly; 1:49 from the start of the first injection to the completion of the midazolam injections for Phillips, 2:24 for Otte, and 2:29 for Van Hook. It also appears that the State is finishing (let alone starting) its potassium chloride injections rather quickly after it finishes the injection of midazolam; 7:14 for Phillips, 8:26 for Otte, and 8:19 for Van Hook.
- 54. It is my expert opinion, to a reasonable degree of scientific certainty, that it is sure or very likely that such a large volume of midazolam will cause a delay in the onset of peak sedative effect such that peak sedative effect will not be achieved by the time the potassium chloride is completely injected, let alone when those injections start.
- 55. By extension, it is also my expert opinion, to a reasonable degree of scientific certainty, that it is sure or very likely that such a large dose of midazolam will delay onset of the peak sedative effect past the point

- at which the paralytic is injected, and well past the point at which the inmate will be sure or very likely to develop acute pulmonary edema.
- 56. Consequently, it is my expert opinion, to a reasonable degree of scientific certainty, that an inmate executed using Ohio's three-drug midazolam protocol is sure or very likely to feel severe pain and suffering following injection of the protocol's drugs.
- 57. Because midazolam at any dose and over any period of time cannot render an inmate insensate to protect him from the severe pain and suffering that will follow with Ohio's protocol, the dose at which the ceiling effect occurs and the time for a large dose such as 500 mg to reach peak sedative effect are functionally irrelevant in the execution context.

### II. Large doses of IV-injected midazolam and Pulmonary Edema

- 58. Once again, I stand behind and fully adopt the opinions and explanations expressed on this topic provided in my previous reports.

  (See Greenblatt Expert Report, ECF No. 1956; Greenblatt Amended Expert Report, ECF No. 1976-3; Greenblatt Expert Rebuttal Report, ECF No. 2003; Greenblatt Testimony, ECF No. 2113, PageID 104162–263.)
- 59. I also reiterate my previous opinion that the effects of pulmonary edema on the condemned inmate will be severely painful and

horrifying. The oxygen deprivation associated with acute pulmonary edema produced by peripheral IV injection of 500 mg of midazolam would not in any way reduce the level of suffering that the inmate will be sure or very likely to fully experience from the effects of the pulmonary edema itself, or the effects of the second and third drugs.

# III. Additional Matters Regarding Ohio's Three-drug Midazolam Lethal Injection Protocol.

- 60. I note the arguments that the State of Ohio has made in its brief filed in the Sixth Circuit case *Henness v. DeWine*, No. 19-3064, arguing that there is no evidence that using Ohio's three-drug midazolam protocol will cause an inmate to experience severe pain and suffering. In my opinion, those arguments fundamentally misstate the science by suggesting that there is a level of unconsciousness short of general anesthesia at which the pain caused by Ohio's current lethal injection protocol is somehow lessened or mitigated.
- 61. The State of Ohio argues in its *Henness* brief that the "question is whether the inmate's subjective, conscious experience is comparable to that of a fully conscious, non-medicated person being exposed to constitutionally impermissible pain. It makes no difference whether the inmate 'senses' pain if midazolam alters his mental state to bring the 'level of pain' below the constitutional limit." (Brief of State Appellees, *Henness v. DeWine*, p. 56.) The State likewise argues the "question is not *whether* the inmates experience the pain, but rather

what the subjective experience would be like." (Id. at p. 57.) The State also argues that "since midazolam is at least *capable* of altering subjective experience, the question becomes whether an inmate injected with 500 milligrams of an experience-altering drug would subjectively experience the sort of pain, 'terror, fear, and disgrace' relevant for Eighth Amendment purposes." (Id. at p. 58.) The State made the same argument throughout the remainder of its brief, including the following assertion: the evidence about midazolam's inabilities "is not legally relevant absence evidence of the inmate's subjective experience. . . . none of that ultimately makes any difference: 'the fact that an inmate was not insensate to pain does not prove he was experience pain or what level of pain he was experiencing." Id. at 65-66.) The State makes the same argument as to the risk of pain from the second and third drugs, stating that it "does not matter whether midazolam stops 'the pain incident to the second and third drugs from reaching the brain of the condemned inmate, . . . if the subjective experience of that pain is not 'serious' in Eighth Amendment terms." (*Id.* at 66–67.)

62. But, to be blunt, that basic argument is not real, actual science. That is simply not the way that sedation, consciousness, and sensation work. The fact that an inmate was not insensate to pain *does* prove, by definition, that he was experiencing that pain. It also proves that he was experiencing the full scope of the pain involved. In the context

- of Ohio's execution protocol, that pain is severe. Because midazolam does not stop the pain incident from the second and third drugs (or from the pulmonary edema) from reaching the brain of the condemned inmate, the experience of that inmate will be the same as any other person—that of severe pain and horrific suffering.
- 63. Put simply, in the absence of either an opioid analgesic drug or unconsciousness to the depth at which unconsciousness and insensateness occur together—*i.e.*, unconsciousness at the depth of general anesthesia—the inmate's subjective experience of pain is the same as a "fully conscious, non-medicated person being exposed to constitutionally impermissible pain," because in that situation there is nothing to blunt the pain.
- 64. Consciousness is a spectrum. But sensation is the crucial consideration when the question is whether Ohio's current execution protocol will subject the inmate to severe pain and suffering, and sensation is binary; one is either sensate or one is not. If the inmate is not insensate—if he remains sensate—he will experience the full scope of the severe pain and horrific suffering caused by the drugs in Ohio's protocol. The inmate can only be made insensate in one of two ways, as I explained at length in my previous expert report and testimony, which I adopt in full here. To summarize, the State could administer an opioid analgesic drug, or it could suppress the inmate's

- consciousness so deeply that unconsciousness and insensateness occur, which is the state of general anesthesia.
- 65. But Ohio's protocol does not create insensateness in either of those two ways. Midazolam, regardless of the dose, is neither an analgesic drug nor capable of suppressing and keeping the consciousness to the depth associated with general anesthesia. The inmate will thus remain sensate, regardless of whether he is sedated at even the maximum level that midazolam can create. That means he will experience the full scope of severe pain and suffering, regardless of whether his consciousness level is altered to be something other than fully conscious.
- occurs does not alter the "subjective" experience of pain, regardless of whether one's consciousness is "altered." Altering the consciousness at the depth to which midazolam can produce might restrict the inmate's ability to convey what he is experiencing, such as his ability to respond to the "consciousness checks." But that is an entirely different matter than whether the inmate is actually subjectively feeling the full scope of severe pain and suffering. He will, he just may not be able to express that, due to the sedation or, later, the paralytic drug's effects.

- 67. Midazolam at any dose is not and cannot act as an opioid analgesic.

  Thus, the *only* way it might reduce the level of pain the condemned inmate will be sure or very likely to suffer from Ohio's current three-drug protocol is midazolam can render and keep the inmate unconscious to the depth at which unconsciousness and insensateness occur together. It cannot do that either, regardless of the dose. Consequently, that inmate will experience the full measure of severe pain caused by Ohio's three-drug midazolam protocol. Will midazolam make a person "unconscious"? Yes, it will, but only to a certain level, and that level is not deep enough to effect insensateness. The inmate's subjective experience of that severe pain, even if he is sedated at some level of unconsciousness, will be sure or very likely to be the same as if he were fully conscious because, again, sensation is binary, and midazolam has no analgesic properties.
- 68. Also, I note that whether midazolam is used alone for intubation is irrelevant to the question of whether Ohio's midazolam execution protocol causes the inmate to suffer severe pain. Midazolam is an anterograde amnestic drug, meaning it blocks the formation of memories. Thus, the fact that midazolam can be used to sedate and relax a patient enough to insert a breathing tube in limited situations, and that patient will not remember the pain later, says nothing about whether the drug can actually block pain in the moment. It cannot.

69. The State also has taken the position that my previous testimony was "predicated on the assumption that the inmate sedated with 500 milligrams of midazolam would subjectively experience the pain in precisely the same way as a fully conscious person." (Brief of State Appellees, Henness v. DeWine, p. 67.) But the State is incorrect; that is not an "assumption." Rather, it is a conclusion born of the science involved. Misinterpreting or misrepresenting the science as the State does will not make that conclusion any less scientifically valid or accurate. And repeating on numerous occasions that misinterpretation or misrepresentation of the science as the State does will not make that inaccuracy any more correct. It remains incorrect as a matter of science, no matter how many times the State repeats it.

# IV. Ohio's Executions of Ronald Phillips, Gary Otte, and Robert Van Hook

70. Once again, I stand behind and fully adopt the opinions and explanations expressed on this topic provided in my previous reports. (See Greenblatt Expert Report, ECF No. 1956; Greenblatt Amended Expert Report, ECF No. 1976-3; Greenblatt Expert Rebuttal Report, ECF No. 2003; Greenblatt Testimony, ECF No. 2113, PageID 104162–263.)

### V. Other Executions Using Midazolam

- 71. Once again, I stand behind and fully adopt the opinions and explanations expressed on this topic provided in my previous reports. (See Greenblatt Expert Report, ECF No. 1956; Greenblatt Amended Expert Report, ECF No. 1976-3; Greenblatt Expert Rebuttal Report, ECF No. 2003; Greenblatt Testimony, ECF No. 2113, PageID 104162–263.)
- 72. There have been four additional executions using a three-drug midazolam protocol since my previous testimony in this case. And the two written autopsy reports I have seen confirm that the inmate developed pulmonary edema in both of those executions—that of Donnie Johnson in Tennessee, and Dominique Ray in Alabama. It is my understanding that there was also an autopsy performed on the other two executed inmates—Michael Samra and Christopher Price, both in Alabama—and I reserve the ability to update this report as applicable when the written autopsy reports for those executions become available.

# SCIENTIFIC BASES AND OPINIONS REGARDING SCIENTIFIC DATA COLLECTION AND USAGE, AND OTHER MATTERS OF SCIENTIFIC CONSENSUS

73. Once again, I stand behind and fully adopt the opinions and explanations expressed on this topic provided in my previous reports.

(See Greenblatt Expert Report, ECF No. 1956; Greenblatt Amended

Expert Report, ECF No. 1976-3; Greenblatt Expert Rebuttal Report, ECF No. 2003; Greenblatt Testimony, ECF No. 2113, PageID 104162–263.)

# SCIENTIFIC BASES AND OPINIONS RELATED TO MR. JACKSON'S ALLEGED ALTERNATIVE LETHAL INJECTION PROTOCOLS

- 74. I am aware of the Court's previously stated concern that alternative lethal injection protocols like those Mr. Jackson alleges here might not reduce the risks of severe pain posed by Ohio's three-drug midazolam protocol. I disagree, however, that there is reasonable scientific basis to be concerned.
- 75. I am also aware of the Court's stated concern that alternative lethal injection protocols that include an overdose of a barbiturate, an opiate, or a benzodiazepine might cause the inmate to develop and suffer the severely painful, torturous sensations of pulmonary edema in the same way an inmate executed with Ohio's three-drug midazolam protocol would. Again, I disagree, because there is ample scientific evidence to allay the Court's concerns.
- 76. It is my expert opinion, to a reasonable degree of medical certainty, that any of the lethal injection alternative protocols that Mr. Jackson has alleged would significantly reduce the several risks of severe pain that Ohio's current three-drug midazolam protocol presents.

- 77. None of Jackson's alternatives include a paralytic drug or potassium chloride. Thus, it is axiomatic that none of Jackson's lethal injection alternatives would pose any of the risks of severe pain and suffering that those drugs in Ohio's current protocol pose, thereby eliminating and thus substantially reducing those risks.
- 78. There are at least three crucial differences between Ohio's current three-drug midazolam protocol and Mr. Jackson's alleged alternatives that virtually eliminate any risk of the condemned inmate remaining sensate to, and thus suffering, the severe pain from pulmonary edema inflicted by the current protocol.
- 79. First, the inmate would be entirely insensate, unaware, and unconscious after administration of any of the alternative protocols.

  Unlike Ohio's reliance on midazolam in the current Ohio execution protocol, each of the lethal injection alternatives includes a drug that that will make the inmate insensate.
- 80. Keep in mind the distinction between being "unconscious" and "insensate" that I explained in my previous report in this case (see ECF No. 1976-3, PageID 88239–242, ¶¶ 108–110), and above in the previous section. Just because an inmate is "unconscious" does not mean he is insensate. To reiterate, consciousness is assessed on a spectrum, but sensation is binary. That means as long as the inmate remains sensate, he can still feel and experience pain, even if he is

- sedated as to appear "unconscious." That also means that unless the inmate is insensate, he will be exposed to the severe pain and suffering caused by Ohio's current execution protocol, including the pain from developing non-cardiogenic pulmonary edema and the pain associated with the second and third drugs.
- 81. Thus, the central question is whether there is anything in a lethal injection protocol that will make the inmate insensate rapidly enough that he is insensate before sources of severe pain become applicable.

  In Ohio's current protocol, there is absolutely nothing that will do that.
- 82. As I explained previously, there are only two ways in the execution context to ensure that an inmate is insensate: 1) administer an opioid analgesic pain-blocking drug; or 2) administer a drug like a barbiturate or a general anesthetic that results in deep enough sedation such that the inmate is both unconscious and insensate.

  That level of sedation is *only* achievable at the level of unconsciousness known as general anesthesia. In the absence of an opioid analgesic pain-blocking drug, it does not matter where an inmate lies on the consciousness spectrum if he is not past the point of unconsciousness associated with general anesthesia: he will remain sensate to the severe pain and suffering caused by acute pulmonary edema, the paralytic, and the potassium chloride.

- 83. As I have explained, there is no reasonably debatable question, based on the pharmacology and pharmacokinetics of midazolam, that midazolam, at any dose, does not function as an analgesic drug, and it cannot depress the consciousness to the depth at which insensateness occurs.
- 84. But the two lethal injection alternatives that Jackson alleges do include a way by which the inmate would be made insensate before the severe pain of pulmonary edema might develop, if at all.
- 85. The secobarbital alternative includes a large overdose of secobarbital, which is a barbiturate. Dobos JK, Phillips J, Covo GA. Acute barbiturate intoxication. JAMA. 1961;176:268-272; Hadden J, Johnson K, Smith S, Price L, Giardina E. Acute barbiturate intoxication. Concepts of management. JAMA. 1969;209(6):893-900; Greenblatt DJ, Allen MD, Harmatz JS, Noel BJ, Shader RI. Overdosage with pentobarbital and secobarbital: assessment of factors related to outcome. J Clin Pharmacol. 1979;19(11-12):758-768. That will cause the inmate to become so deeply unconscious as to be unconscious at the level at which insensation occurs. That would protect the inmate against the severe pain and suffering from any pulmonary edema that might subsequently develop at a later time.

- 86. The four-drug morphine alternative includes a large overdose of morphine, which is an opioid analgesic. Glare PA, Walsh TD. Clinical pharmacokinetics of morphine. Ther Drug Monit. 1991;13(1):1-23.

  The morphine is a true pain-blocking drug, acting on the body's pain receptors, and it will therefore protect the inmate against the severe pain and suffering from any pulmonary edema that might subsequently develop at a later time.
- 87. Second, the inmate would be made insensate, unaware, and unconscious relatively quickly after oral administration of the alternative protocols. By contrast, Ohio's current three-drug protocol will never cause insensateness, at any time following injection.
- 88. The onset of action of oral secobarbital is rapid. After administration of usual therapeutic doses, effects are maximal within one hour, although the onset of those effects occurs much quicker. After a very large dose, like 10 grams, extreme central nervous depression is very likely to be produced rapidly as well. Epstein LC, Lasagna L., A comparison of the effects of orally administered barbiturate salts and barbiturate acids on human psychomotor performance. J Pharmacol Exp Ther. 1968;164(2): 433-441; Bloomfield SS, Tetreault L, Lareniere B, Bordeleau JM., A method for the evaluation of hypnotic agents in man. The comparative hypnotic effects of secobarbital, methaqualone and placebo in normal subjects and in psychiatric patients, J

- Pharmacol Exp Ther. 1967;156(2): 375-382; Urbach KF., Hypnotic properties of amitriptyline: comparison with secobarbital, Anesth Analg. 1967;46(6):835-842.
- 89. The same rapid onset of effect and of maximum effect is true following oral administration of morphine in therapeutic doses and in overdoses such as 15 grams of morphine. Glare PA, Walsh TD, Clinical pharmacokinetics of morphine, Ther Drug Monit. 1991;13(1):1-23.
- 90. Third, the inmate would not develop the same type of pulmonary edema, at the same speed, or for the same reasons, as inmates are developing pulmonary edema during executions that involve IV-injected massive doses of midazolam.
- 91. Acute pulmonary edema following high-dose intravenous midazolam is a direct irritant effect of the intravenous solvent (the acidic midazolam) on lung tissue, causing a failure of barrier function of capillary endothelial cells. That results in leakage of intravascular fluid into the alvoli, where oxygen-CO2 exchange is supposed to happen. That is a non-cardiogenic genesis of pulmonary edema, because it has nothing to do with cardiac functions. *See* Mattu A, Martinez JP, Kelly BS, Modern management of cardiogenic pulmonary edema, Emerg Med Clin North Am. 2005;23(4):1105-1125; Perina DG., Noncardiogenic pulmonary edema, Emerg Med Clin North Am. 2003;21(2):385-393.

- 92. The inmate who develops this non-cardiogenic pulmonary edema from Ohio's current protocol will remain sensate to that severe pain and suffering. Again, an inmate executed with midazolam as the first drug in Ohio's current protocol will *never* be made insensate, because none of the drugs in the protocol is a pain-blocking drug and none of the drugs can suppress the consciousness to the level at which insensateness occurs. Thus, an inmate who develops non-cardiogenic pulmonary edema following IV injection of a high dose of midazolam will remain sensate to the severe pain and suffering of acute pulmonary edema throughout the remainder of his execution.
- 93. In contrast, pulmonary edema associated with oral barbiturate or opioid overdosage obviously can't involve that mechanism, since there is no intravenous solvent involved. The drugs are administered into the gastro-intestinal tract, not infused into peripheral veins. It is true that overdoses of barbitruates or opioids or benzodiazepines might cause pulmonary edema to develop eventually. But any pulmonary edema that might develop from overdoses of those drugs administered orally is due to a failure of cardiac function and blood pressure regulation, and can be called cardiogenic. *See* Mattu A, Martinez JP, Kelly BS, Modern management of cardiogenic pulmonary edema, Emerg Med Clin North Am. 2005;23(4):1105-1125; Perina DG., Noncardiogenic pulmonary edema, Emerg Med Clin North Am. 2003;21(2):385-393. Pulmonary edema is an end-stage consequence

- of lethal systemic and CNS exposure to the barbiturate or opioid, leading to inadequate cardiac output, pressure imbalance between left and right heart, and consequent pulmonary congestion and edema.
- 94. A key distinction between cardiogenic pulmonary edema in this situation and the non-cardiogenic pulmonary edema that develops with Ohio's current protocol is that the cardiogenic pulmonary edema would develop much more slowly, because it depends on impairment of heart function (force of contractions), and failure of blood vessels in the rest of the body's circulation to maintain enough resistance and support blood pressure. As a result, there is a back-up of fluid which leaks into lung tissue, which causes the (cardiogenic) pulmonary edema to develop.
- 95. The crucial takeaway from this is that an inmate who develops cardiogenic pulmonary edema after injection of any of Jackson's lethal injection alternatives would not remain sensate at that time, because the morphine or secobarbital would have rendered him insensate well before that pulmonary edema develops. Thus, unlike the demonstrated likelihood of the inmate suffering the severe pain of non-cardiogenic acute pulmonary edema with Ohio's current protocol, there is little to no risk that the inmate would suffer from severe pain of any cardiogenic acute pulmonary edema that might develop under Jackson's alternatives.

- 96. To summarize: an inmate executed using Ohio's current three-drug protocol will:
  - A. Remain sensate throughout the duration of his execution because there is no pain-blocking drug in the protocol, and
  - B. almost immediately begin to develop and suffer the horrifying sensations of acute non-cardiogenic pulmonary edema that is
  - C. caused by the large amount of highly acidic drug injected directly into his blood stream through a peripheral IV, which travels, unbuffered to a neutral pH, from there to the lungs in seconds, irritating and disrupting the delicate lung tissues and capillaries.
- 97. On the other hand, an inmate executed using Mr. Jackson's alleged lethal injection alternative protocols will:
  - A. Be quickly rendered insensate, unaware, and unconscious shortly after ingesting the drug(s), because there is a true pain-blocking drug administered, and
  - B. not experience the severe pain and suffering of any pulmonary edema that develops, because he is insensate and any pulmonary edema that develops will develop quite gradually, if at all, well after the inmate is insensate, in the form of cardiogenic pulmonary edema,
  - C. caused by the respiratory suppressant effects of the drugs, not a direct action on the lung tissues and capillaries themselves.

98. Additionally, the time from ingestion of the alternative drugs until the drugs start to take effect and reach maximum effect—and thus the time from ingestion until death—can be decreased by injecting the drugs directly into the duodenum rather than into the stomach. This can be accomplished through the use of a feeding tube with a weighted tip. Injecting the drugs directly into the duodenum places the drugs into the part of gastrointestinal track where the drugs are absorbed into the bloodstream. The net result is that the onset of all drug effects would be accelerated. However, unconsciousness and the insensate condition would still occur before cardiac output failure and any cardiogenic pulmonary edema. The sequence of effects on the inmate would be the same, but of faster onset.

## CONCLUSION

- My expert opinions are contained throughout this report, as well as my previous reports and testimony, which are fully incorporated here by reference. (See Greenblatt Expert Report, ECF No. 1956;
  Greenblatt Amended Expert Report, ECF No. 1976-3; Greenblatt Expert Rebuttal Report, ECF No. 2003; Greenblatt Testimony, ECF No. 2113, PageID 104162–263.)
- 100. Some of them are reiterated as follows.
- 101. It is my expert opinion that once the maximum sedative effect of 500 mg of IV injected midazolam is reached, an inmate will nevertheless

- remain sensate and is sure or very likely to experience the severe pain and suffering associated with the drugs in the protocol.
- 102. It is my expert opinion that there is no analgesic property to midazolam, and midazolam at any dosage is unable to put the inmate in a state of being so deeply sedated as to be unconscious and insensate at once. Or, stated differently, it is my expert opinion that IV-injected midazolam, at any dose, will never be able to make an inmate insensate as is necessary to avoid subjecting that inmate to the severe pain and suffering associated with the drugs in Ohio's execution protocol, and larger doses actually increase the risk of pain and suffering to which the inmate will be subjected.
- 103. It is my expert opinion that a consensus exists among those with the most relevant training and experience in clinical pharmacology that supports my conclusions about midazolam's limitations contained throughout this report.
- 104. It is my expert opinion that the primary cause of the pulmonary edema identified in most of the inmates executed using a lethal injection cocktail including large doses of IV-injected midazolam is its acidic solution. That acid enters the lungs following IV injection, and immediately begins irritating the pulmonary blood vessels and leakage of fluid into spaces where air exchange occurs. The result is that the

- lungs immediately begin to fill with fluid, which will continue even after the midazolam is buffered to a neutral pH.
- 105. It is my expert opinion that acute pulmonary edema is a terrifying condition, and that it causes the inmate to endure great suffering as he will struggle to breathe with damaged lungs that cannot exchange air.
- 106. It is my expert opinion that injecting large doses of midazolam in IV injection solution will cause severe burning sensations in the blood vessels due to the acidic nature of the midazolam in that form.
- 107. It is my expert opinion that an inmate who is subjected to Ohio's Execution Protocol, including Plaintiff Henness, is certain or very likely to experience acute pulmonary edema after peripheral IV injection of 500 mg or more of midazolam.
- 108. It is also my expert opinion that an inmate who is subjected to Ohio's Execution Protocol, including Plaintiff Henness, is certain or very likely to remain sensate to the severe pain and suffering associated with acute pulmonary edema.
- 109. It is also my expert opinion that an inmate who is subjected to Ohio's Execution Protocol, including Plaintiff Henness, is certain or very likely to remain sensate to the severe pain and suffering associated with peripheral IV injection of 500 mg or more of midazolam.

- 110. It is also my expert opinion that an inmate who is subjected to Ohio's Execution Protocol, including Plaintiff Henness, is certain or very likely to remain sensate to the severe pain and suffering associated with injecting the second and third drugs.
- 111. It is also my expert opinion that an inmate who is subjected to Ohio's Execution Protocol, including Plaintiff Jackson, is certain or very likely to remain sensate to the severe pain and suffering associated with the actions of the second and third drugs.
- 112. It is my expert opinion that a consensus exists among scientifically trained persons that additional data that is confirmatory is of great importance for establishing scientific "truth," and, accordingly, such "cumulative" data is highly relevant to appropriately conducted medical and scientific research.
- 113. It is my expert opinion that the executions the courts have previously described as having been without problems were not, as a matter of scientific fact, without problems; almost all of the inmates in the Florida executions developed acute pulmonary edema, and inmate Warner described the pain from injection of a large volume of acidic midazolam in IV injection solution as causing him to feel as if his body was on fire.

- Jackson has alleged would significantly reduce the substantial risks of the inmate experiencing the full scope of pain from several different sources of severe pain and suffering caused by Ohio's current protocol, including, among others, the pain and suffering from non-cardiogenic acute pulmonary edema, from the burning pain following peripheral IV injection of 500 mg midazolam, from the horrific suffocation caused by the paralytic drug, and from the burning pain upon IV injection of a large dose of potassium chloride.
- 115. It is my expert opinion that the lethal injection alternatives that

  Jackson has alleged would significantly reduce the substantial risks

  of the inmate experiencing any pulmonary edema caused by the

  alleged alternatives as compared to the risk of pain from the inmate

  developing pulmonary edema following administration of Ohio's

  current three-drug protocol.
- 116. It is my expert opinion that any pulmonary edema that might develop following oral administration of Jackson's alleged alternatives would be cardiogenic pulmonary edema, not the non-cardiogenic pulmonary edema that Ohio's current three-drug execution protocol causes. It is also my expert opinion that there is virtually no risk that Jackson would remain sensate to experience any pain or suffering from the cardiogenic pulmonary edema that might develop with his alleged

- alternatives, unlike the sure or very likely risk that he will experience the full measure of severe pain and suffering from the non-cardiogenic pulmonary edema that Ohio's current protocol causes.
- 117. It remains my expert opinion that if an inmate is not rendered and kept insensate during his execution, then that inmate will be sure or likely to experience and be subjected to the full measure of severe pain and suffering caused by the drugs in Ohio's lethal injection protocol. Because he will remain fully sensate, there is no difference in terms of pain sensation and subjective experience between an inmate given 500 mg of IV injected midazolam and one who is otherwise fully conscious and not made insensate. Whether the inmate's consciousness is "altered" by the midazolam is utterly irrelevant to whether he will remain sensate to the full measure of severe pain and suffering that Ohio's current protocol causes.
- 118. I hold the opinions expressed throughout this expert report to a high degree of medical and scientific certainty. I understand that discovery remains ongoing, and I reserve the right to amend or supplement my report upon provision of additional information that so warrants, including but not limited to deposition testimony and additional documents.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: July 9, 2019

Boston, Massachusetts

Good J. Gentlat

/s/ Dr. David J. Greenblatt, M.D.

Dr. David J. Greenblatt, M.D.

07/09/2019

# David J. Greenblatt, M. D. July 9, 2019

## Deposition or Trial Testimony In Last 4 Years

2/5/2014

Deposition

Washington, DC

Shire LLC, et al vs. Amneal, LLC et al and Watson Inc. et al

U. S. District Court, District of New Jersey

C. A. No. 2:11-cv-03781 (SRC)(CLW) (Consolidated)

C. A. No. 2: 12-cv-00083-SRC-CL W

4/2/2014

Trial

Brockton, MA

Vasa and Plante vs. Compass et al

Plymouth SS Superior Court, Commonwealth of Mass.

C. A. No. 2007-01394-A and 2010-01309-B (consolidated)

4/6/2015 Trial

Fall River, MA

Commonwealth vs. Aaron Hernandez

Bristol, SS., Fall River Superior Court

Indictments 2013-00983

10/14/2015

Deposition

Boston, MA

Williams vs. Maratachi

Circuit Court of the 17th Judicial Circuit, Broward County, FL

Case No.: CACE 12010166

6/20/2016

Trial

Brockton, MA

Baggia vs. Grotz et al

Plymouth SS. Superior Court, Commonwealth of Mass.

Civil Action No. 11-00414-A

9/19/2016

Trial

Derry, NH

State vs. Brian Webb

New Hampshire Judicial Branch, 10th Circuit, Derry, NH

10/27/2016

Trial

Boston, MA

Hi-Tech Pharmaceuticals vs. Pieter A. Cohen, M. D. et al United States District Court, District of Massachusetts

Docket No. 1:16-cv-10660-WGY

2/14/2017

Trial

Miami FL

United States vs. Christopher R. Glenn

U.S. District Court, Southern District of Florida

Case No. 15-CR-20632-RNS(s)

3/13/2017

Trial

Dedham MA

Thou (adm. estate of S. Chin) vs. Russo

Commonwealth of Massachusetts, Norfolk Superior Court

Docket Number 1382CV00638

10/11/2017

Deposition

Boston MA

McDevitt vs. Boehringer Ingelheim, Inc.

Superior Court J. D. at Hartford

Docket No. CPL-HHD-CV-15-6057664S (CLD X03)

11/13/2017

Deposition

Dedham MA

van Dyke et al vs. van Hemelrijk etr al

State of Rhode Island and Providence Plantations

Washington SC Superior Court

C. A. No.: WC/13-506

1/25/2018
Deposition
Washington DC
AstraZeneca vs. Amneal
U. S. District Court for the District of Delaware
Civil Action No. 15-1056-RGA and 15-1000-RGA

6/15/2018
Deposition
Boston, MA
Abu-Ali Abdur'Rahman et al v. Tony Parker et al
Chancery Court for State of Tennessee, Twentieth Judicial District, Davidson
County, TN, Part III
Case No. 18-183-II (III)

7/9/2018
Deposition
Boston MA
Kolner vs. Federal Express Corp, et al
Circuit Court of 19th Judicial Circuit, Indian River County, FL
Case No. 312014CA001208XXXXXX

7/10/2018 & 7/16/2018
Trial
Nashville, TN
Abu-Ali Abdur'Rahman et al v. Tony Parker et al
Chancery Court for State of Tennessee, Twentieth Judicial District, Davidson
County, TN, Part III
Case No. 18-183-II (III)

9/20/2018 Trial Salem, NH State of New Hampshire vs. Jeffrey Adams

12/10/2018
Trial
Philadelphia, PA
United States vs. Emma Semler
U. S. District Court, Eastern District of Pennsylvania
CRIM. No. 17-CR-120

12/12/2018
Hearing
Dayton, OH
In re Ohio Execution Protocol Litigation
U.S. District Court, Southern District of Ohio
Case No. 2:11-cv-1016

#### CURRICULUM VITAE

## DAVID J. GREENBLATT, M.D.

## Current Title:

Louis Lasagna Endowed Professor, Department of Immunology (formerly the Department of Pharmacology and Experimental Therapeutics); Professor of Psychiatry, Medicine, and Anesthesia, Tufts University School of Medicine; Special and Scientific Staff (Research), Tufts Medical Center, Boston MA

### Education and Training:

1966	B.A. Amherst College (magna cum laude)
1970	M.D. Harvard Medical School
1970-1971	Medical Intern, Montefiore Hospital and Medical Center, Bronx, NY
1971-1972	Assistant Medical Resident, Harvard Medical Service, Boston City Hospital
1972-1974	Research Fellow in Pharmacology, Harvard Medical School; Fellow in Medicine (Clinical Pharmacology), Massachusetts General Hospital

#### Professional Appointments:

## Harvard Medical School and Massachutte General Hospital

1974-1979	Assistant Professor of Medicine, Harvard Medical School;
	Assistant in Medicine, Massachusetts General Hospital
1976-1979	Chief, Clinical Pharmacology Unit,
1970 1979	Massachusetts General Hospital

## Tufts University School of Medicine (TUSM) and Tufts Medical Center (TMC):

1979-present	Professor of Psychiatry, Tufts University School of
	Medicine, Boston MA (TUSM)
1979-2015	Associate Medical Staff, Tufts Medical Center (TMC)
2015-	Special and Scientific Staff (Research), TMC
1979-1984	Associate Professor of Medicine, TUSM
1983-1996, 2001-2002	Chair, Institutional Review Board, TMC/TUSM
1984-present	Professor of Medicine, TUSM
1988-1991	Professor of Pharmacology, TUSM
1991-present	Professor of Pharmacology and Experimental Therapeutics
	(with tenure), TUSM
1994-2010	Chairman, Department of Pharmacology and Experimental
	Therapeutics, TUSM
1995-present	Professor of Anesthesia, TUSM
1995-2002	Program Director, General Clinical Research Center, TMC

1997-present	Louis	Lasagna	Endowed	Professor	of	Pharmacology	and

Experimental Therapeutics, TUSM

2002-2010 Associate Program Director, Clinical/Translational

Research Center, TMC/TUSM

Awards	and	Honors:
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Awards and	Honors:
1972-74	Research Fellow of the Medical Foundation, Inc., Boston
1978-87	Pfizer Lecturer in Clinical Pharmacology (at various institutions)
1980	Rawls-Palmer Progress in Medicine Award and Lecture, American Society for Clinical Pharmacology and Therapeutics
1980	Clinical Pharmacology Unit Developmental Grant, Pharmaceutical Manufacturers' Association Foundation, Washington, D.C.
1981	Wellcome Visiting Professor in the Basic Medical Sciences (the Burroughs Wellcome Fund and Federation of American Societies for Experimental Biology), East Carolina University School of Medicine, Greenville, N.C.
1983	Paul Ehrlich Visiting Professor of Clinical Pharmacology, University of Miami School of Medicine
1984	Sterling Visiting Professor, Boston University School of Medicine
1985	The McKeen Cattell Award, (with Drs. 0. Bellmann, H.R. Ochs, and M. Knüchel) American College of Clinical Pharmacology
1988	T. George Bidder Distinguished Lectureship in Psychopharmacology, University of California at Los Angeles
1997	Pfizer Visiting Professor of Clinical Pharmacology, Morehouse University School of Medicine, Atlanta, GA
2001	Distinguished Service Award, American College of Clinical Pharmacology
2002	Distinguished Investigator Award, American College of Clinical Pharmacology
2005	Research Achievement Award in Clinical Sciences, American Association of Pharmaceutical Scientists
2013	Outstanding Speaker Award, American Association for Clinical Chemistry
2015	Distinguished Faculty Award, Tufts University School of Medicine
2016	Award in Excellence in Clinical Pharmacology, Pharmaceutical Research and Manufacturers of America Foundation
2016	Man of Good Conscience Award, Association of Women Psychiatrists

#### Certification

1991 American Board of Clinical Pharmacology, Inc.

## Editorial Boards

Journal of Clinical Psychopharmacology (Co-Editor-in-Chief)

Clinical Pharmacology in Drug Development (Editor-in-Chief)

Journal of Clinical Pharmacology

British Journal of Clinical Pharmacology (2011-2016)

Biopharmaceutics and Drug Disposition

Xenobiotica

Neuropsychopharmacology (1986-1990)

Drug Investigation

Drugs and Aging

Pharmacology and Toxicology

Drugs and Therapy Perspectives

## Professional Societies

American Society for Clinical Investigation (Emeritus)

American Society for Pharmacology and Experimental Therapeutics

American Federation for Clinical Research

American Society for Clinical Pharmacology and Therapeutics Board of Directors, 1983-85

American College of Clinical Pharmacology
Board of Regents, 1981-85, 1987-91;
Honarary Regent, 1994-;
President-Elect, 1994-1996;
President, 1996-1998

American College of Neuropsychopharmacology (Fellow) (1974-2011)

International Society for the Study of Xenobiotics

British Pharmacological Society

#### ORIGINAL RESEARCH ARTICLES

- 1. Tursky B, Greenblatt DJ: Local vascular and thermal changes that accompany electric shock. Psychophysiology 3:371-380, 1967.
- 2. Greenblatt DJ, DiMascio A, Messier M, Stotsky B: Magnesium pemoline and job performance in mentally handicapped workers. Clinical Pharmacology and Therapeutics 10:530-533, 1969.
- 3. Greenblatt DJ, Tursky B: Local vascular and impedence changes induced by electric shock. American Journal of Physiology 216:712-718, 1969.
- 4. Tursky B, Greenblatt DJ, O'Connell DN: Electrocutaneous threshold changes produced by electric shock. Psychophysiology 7:490-498, 1970.
- 5. Greenblatt DJ, Shader RI: Psychopharmacologic management of anxiety in the cardiac patient. Psychiatry in Medicine 2:490-498, 1970.
- 6. Greenblatt DJ, Shader RI: Meprobamate: a study of irrational drug use. American Journal of Psychiatry 127:1297-1303, 1971.
- 7. Greenblatt DJ, Shader RI: The clinical choice of sedative-hypnotics. Annals of Internal Medicine 77:91-100, 1972.
- 8. Greenblatt DJ, Shader RI: On the psychopharmacology of beta adrenergic blockade. Current Therapeutic Research 14:615-625, 1972.
- 9. Greenblatt DJ, Koch-Weser J: Adverse reactions to spironolactone: a report from the Boston Collaborative Drug Surveillance Program. Journal of the American Medical Association 225:40-43, 1973.
- 10. Greenblatt DJ, Shader RI: Anticholinergics. New England Journal of Medicine 288:1215-1219, 1973.
- 11. Greenblatt DJ, Koch-Weser J: Adverse reactions to propranolol in hospitalized medical patients: a report from the Boston Collaborative Drug Surveillance Program. American Heart Journal 86:478-484, 1973.
- 12. Greenblatt DJ, Koch-Weser J: Adverse reactions to intravenous diazepam: a report from the Boston Collaborative Drug Surveillance Program. American Journal of Medical Sciences 266:261-266, 1973.
- 13. Greenblatt DJ, Duhme DW, Koch-Weser J, Smith TW: Evaluation of digoxin bioavailability in single-dose studies. New England Journal of Medicine 289:651-654, 1973.
- 14. Greenblatt DJ, Koch-Weser J: Adverse reactions to beta-adrenergic receptor blocking drugs: a report from the Boston Collaborative Drug Surveillance Program. Drugs 7:118-129, 1974.
- 15. Greenblatt DJ, Shader RI: Drug abuse and the emergency room physician. American Journal of Psychiatry 131:559-562, 1974.
- 16. Duhme DW, Greenblatt DJ, Koch-Weser J: Reduction of digoxin toxicity associated with measurement of serum levels: a report from the Boston Collaborative Drug Surveillance Program. <u>Annals of Internal Medicine</u> 80:516-519, 1974.
- 17. Koch-Weser J, Duhme DW, Greenblatt DJ: Influence of serum digoxin concentration measurements on frequency of digitoxicity. Clinical Pharmacology and Therapeutics 16:284-287, 1974.

- 18. Greenblatt DJ, Duhme DW, Koch-Weser J, Smith TW: Intravenous digoxin as a bioavailability standard: slow infusion and rapid injection. Clinical Pharmacology and Therapeutics 15:510-513, 1974.
- 19. Greenblatt DJ, Koch-Weser J: Oral contraceptives and hypertension: a report from the Boston Collaborative Drug Surveillance Program.

  Obstetrics and Gynecology 44:412-417, 1974.
- 20. Greenblatt DJ, Duhme DW, Koch-Weser J, Smith TW: Equivalent bioavailability from digoxin elixir and rapid-dissolution tablets. Journal of the American Medical Association 229:1774-1776, 1974.
- 21. Greenblatt DJ, Shader RI, Koch-Weser J. Pharmacokinetic determinants of the response to single doses of chlordiazepoxide. American Journal of Psychiatry 131:1395-1397, 1974.
- 22. Greenblatt DJ, Koch-Weser J: Clinical toxicity of chlordiazepoxide and diazepam in relation to serum albumin concentration: a report from the Boston Collaborative Drug Surveillance Program. European Journal of Clinical Pharmacology 7:259-262, 1974.
- 23. Greenblatt DJ, Duhme DW, Koch-Weser J, Smith TW: Bioavailability of digoxin tablets and elixir in the fasting and postprandial states. Clinical Pharmacology and Therapeutics 16:444-448, 1974.
- 24. Greenblatt DJ, Shader RI, Koch-Weser J, Franke K: Slow absorption of intramuscular chlordiazepoxide. New England Journal of Medicine 291:1116-1118, 1974.
- 25. Greenblatt DJ, Duhme DW, Koch-Weser J, Smith TW: Comparison of one- and six-day urinary digoxin excretion in single-dose bioavailability studies. Clinical Pharmacology and Therapeutics 16:813-816, 1974.
- 26. Greenblatt DJ, Shader RI: Benzodiazepines. New England Journal of Medicine 291:1011-1015, 1239-1241, 1974.
- 27. Greenblatt DJ, Shader RI, Koch-Weser J: Flurazepam hydrochloride. Clinical Pharmacology and Therapeutics 17:1-14, 1975.
- 28. Sokol GH, Greenblatt DJ, Littman P, Franke K, Koch-Weser J: Chlordiazepoxide metabolism in mice following hepatic irradiation. Pharmacology 13:248-251, 1975.
- 29. Greenblatt DJ, Shader RI, Koch-Weser J: Psychotropic drug use in the Boston area: a report from the Boston Collaborative Drug Surveillance program. Archives of General Psychiatry 32:518-521, 1975.
- 30. Shader RI, Greenblatt DJ, Salzman C, Kochansky GE, Harmatz JS:
  Benzodiazepines: safety and toxicity. <u>Diseases of the Nervous System</u> 36(No.5, Sect.2):23-26, (May) 1975.
- 31. Greenblatt DJ, Shader RI, Koch-Weser J: Pharmacokinetics in clinical medicine: oxazepam versus other benzodiazepines. <u>Diseases of the Nervous System</u> 36(No.5, Sect.2):6-13, (May) 1975.
- 32. Greenblatt DJ, Shader RI, Koch-Weser J: Flurazepam hydrochloride, a benzodiazepine hypnotic. <u>Annals of Internal Medicine</u> 83:237-241, 1975.
- 33. Koup JR, Greenblatt DJ, Jusko WJ, Smith TW, Koch-Weser J:
  Pharmacokinetics of digoxin in normal subjects after intravenous bolus and infusion doses. <u>Journal of Pharmacokinetics and Biopharmaceutics</u> 3:181-192, 1975.

- 34. Greenblatt DJ, Koch-Weser J: Clinical pharmacokinetics. New England Journal of Medicine 293:702-705, 964-970, 1975.
- 35. Greenblatt DJ, Allen MD, Koch-Weser J: Accidental poisoning with psychotropic drugs in children. American Journal of Diseases in Children 130:507-511, 1976.
- 36. Greenblatt DJ, Shader RI, Koch-Weser J. Serum creatine phosphokinase concentrations after intramuscular chlordiazepoxide and its solvent. Journal of Clinical Pharmacology 16:118-121, 1976.
- 37. Greenblatt DJ, Bolognini V, Koch-Weser J, Harmatz JS: Pharmacokinetic approach to the clinical use of lidocaine intravenously. <u>Journal of</u> the American Medical Association 236:273-277, 1976.
- 38. Pfeifer HJ, Greenblatt DJ, Koch-Weser J: Clinical use and toxicity of intravenous lidocaine: a report from the Boston Collaborative Drug Surveillance Program. American Heart Journal 92:168-173, 1976.
- 39. Greenblatt DJ, Duhme DW, Koch-Weser J, Smith TW: Assessment of methodology in single-dose studies of digoxin bioavailability. Pharmacology 14:182-190, 1976.
- 40. Greenblatt DJ, Shader RI, Lofgren S: Rational psychopharmacology for patients with medical diseases. <u>Annual Review of Medicine</u> 27:407-420, 1976.
- 41. Greenblatt DJ, Shader RI, Harmatz JS, Franke K, Koch-Weser J: Influence of magnesium and aluminum hydroxide mixture on chlordiazepoxide absorption. Clinical Pharmacology and Therapeutics 19:234-239, 1976.
- 42. Greenblatt DJ, Smith TW, Koch-Weser J: Bioavailability of drugs: the digoxin dilemma. Clinical Pharmacokinetics 1:36-51, 1976.
- 43. Greenblatt DJ, Ransil BJ, Harmatz JS, Smith TW, Duhme DW, Koch-Weser J: Variability of 24-hour urinary creatinine excretion by normal subjects. Journal of Clinical Pharmacology 16:321-328, 1976.
- 44. Stanski DR, Greenblatt DJ, Lappas DG, Koch-Weser J, Lowenstein E: Kinetics of high dose intravenous morphine in cardiac surgery patients. Clinical Pharmacology and Therapeutics 19:752-756, 1976.
- 45. Pfeifer HJ, Greenblatt DJ, Koch-Weser J: Clinical toxicity of reserpine in hospitalized patients: a report from the Boston Collaborative Drug Surveillance Program. American Journal of Medical Sciences 271:269-276, 1976.
- 46. DiMascio A, Bernardo DL, Greenblatt DJ, Marder JE: A controlled trial of amantadine in drug-induced extrapyramidal disorders. Archives of General Psychiatry 33:599.602, 1976.
- 47. Greenblatt DJ, Schillings RT, Kyriakopoulos AA, Shader RI, Sisenwine SF, Knowles JA, Ruelius HW: Clinical pharmacokinetics of lorazepam. I. Absorption and disposition of oral 14C-lorazepam. Clinical Pharmacology and Therapeutics 20:329-341, 1976.
- 48. Stanski DR, Greenblatt DJ, Selwyn A, Shader RI, Franke K, Koch-Weser J: Plasma and cerebrospinal fluid concentrations of chlordiazepoxide and its metabolites in surgical patients. Clinical Pharmacology and Therapeutics 20:571-578, 1976.

- 49. Greenblatt DJ, Koch-Weser J: Intramuscular injection of drugs. New England Journal of Medicine 295:542-546, 1976.
- 50. Greenblatt DJ, Duhme DW, Allen MD, Koch-Weser J: Clinical toxicity of furosemide in hospitalized patients: a report from the Boston Collaborative Drug Surveillance Program. <u>American Heart Journal</u> 94:6-13, 1977.
- 51. Allen MD, Greenblatt DJ: Accidental salicylate poisoning. Paediatrician 6:244-249, 1977.
- 52. Greenblatt DJ, Shader RI, Harmatz JS, Franke K, Koch-Weser J:
  Absorption rate, blood concentrations, and early response to oral
  chlordiazepoxide. American Journal of Psychiatry 134:559-562, 1977.
- 53. Greenblatt DJ, Joyce TH, Comer WH, Knowles JA, Shader RI, Kyriakopoulos AA, MacLaughlin DS, Ruelius HW: Clinical pharmacokinetics of lorazepam. II. Intramuscular injection. Clinical Pharmacology and Therapeutics 21:222-230, 1977.
- 54. Ransil BJ, Greenblatt DJ, Koch-Weser J: Evidence for systematic temporal variation in 24-hour urinary creatinine excretion. <u>Journal of Clinical Pharmacology</u> 17:108-119, 1977.
- 55. Greenblatt DJ, Comer WH, Elliott HW, Shader RI, Knowles JA, Ruelius HW: Clinical pharmacokinetics of lorazepam. III. Intravenous injection (preliminary report). <u>Journal of Clinical Pharmacology</u> 17:490-494, 1977.
- 56. Greenblatt DJ, Knowles JA, Comer WN, Shader RI, Harmatz JS, Ruelius HW: Clinical pharmacokinetics of lorazepam. IV. Long-term oral administation. Journal of Clinical Pharmacology 17:495-500, 1977.
- 57. Ameer B, Greenblatt DJ: Acetaminophen. <u>Annals of Internal Medicine</u> 87:202-209, 1977.
- 58. Greenblatt DJ, Pfeifer HJ, Ochs HR, Franke K, MacLaughlin DS, Smith TW, Koch-Weser J: Pharmacokinetics of quinidine in humans after intravenous, intramuscular and oral administration. <u>Journal of Pharmacology and Experimental Therapeutics 202:365-378, 1977.</u>
- 59. Greenblatt DJ, Allen MD, Shader RI: Toxicity of high-dose flurazepam in the elderly. Clinical Pharmacology and Therapeutics 21:355-361, 1977.
- 60. Greenblatt DJ, DiMascio A, Harmatz JS, Bernardo DL, Marder JR:
  Pharmacokinetics and clinical effects of amantadine in drug-induced
  extrapyramidal symptoms. <u>Journal of Clinical Pharmacology</u> 17:704-708,
  1977.
- 61. Greenblatt DJ, Allen MD, Noel BJ, Shader RI: Acute overdosage with benzodiazepine derivatives. Clinical Pharmacology and Therapeutics 21:497-514, 1977.
- 62. Shader RI, Greenblatt DJ: Clinical implications of benzodiazepine pharmacokinetics. American Journal of Psychiatry 134:652-656, 1977.
- 63. Pfeifer HJ, Greenblatt DJ, Koch-Weser J: Adverse reactions to practolol in hospitalized patients: a report from the Boston Collaborative Drug Surveillance Program. <u>European Journal of Clinical Pharmacology</u> 12:167-170, 1977.
- 64. Allen MD, Greenblatt DJ, Noel BJ: Meprobamate overdosage: a continuing problem. Clinical Toxicology 11:501-516, 1977.

- 65. Greenblatt DJ, Harmatz JS, Stanski DR, Shader RI, Franke K, Koch-Weser J: Factors influencing blood concentrations of chlordiazepoxide: a use of multiple regression analysis. Psychopharmacology 54:277-282, 1977.
- 66. Greenblatt DJ, Shader RI, Franke K, MacLaughlin DS, Ransil BJ, Koch-Weser J: Kinetics of intravenous chlordiazepoxide: sex differences in drug distribution. Clinical Pharmacology and Therapeutics 22:893-903, 1977.
- 67. Shader RI, Greenblatt DJ, Harmatz JS, Franke K, Koch-Weser J:
  Absorption and disposition of chlordiazepoxide in young and elderly
  male volunteers. Journal of Clinical Pharmacology 17:709-718, 1977.
- 68. Greenblatt DJ, Harmatz JS, Shader RI: Sex differences in diazepam protein binding in patients with renal insufficiency. Pharmacology 16:26-29, 1978.
- 69. Ochs HR, Greenblatt DJ, Bodem G, Smith TW: Sprinolactone. American Heart Journal 96:389-400, 1978.
- 70. Pfeifer HJ, Greenblatt DJ: Clinical toxicity of theophylline in relation to cigarette smoking: a report from the Boston Collaborative Drug Surveillance Program. Chest 73:455-459, 1978.
- 71. Greenblatt DJ: Determination of desmethyldiazepam in plasma by electron-capture GLC: application to pharmacokinetic studies of clorazepate. Journal of Pharmaceutical Science 67:427-429, 1978.
- 72. Gayes JM, Greenblatt DJ, Lloyd BL, Harmatz JS, Smith TW: Cerebrospinal fluid digoxin concentrations in humans. <u>Journal of Clinical</u> Pharmacology 18:177-179, 1978.
- 73. Greenblatt DJ, Harmatz JS, Shader RI: Factors influencing diazepam pharmacokinetics. <u>International Journal of Clinical Pharmacology and</u> Biopharmacy 16:177-179, 1978.
- 74. Ochs HR, Bodem G, Bales G, Greenblatt DJ, Smith TW: Increased Clearance of digoxin in rabbits during repeated administration. <u>Journal of</u>
  Pharmacology and Experimental Therapeutics 205:516-524, 1978.
- 75. Ochs HR, Greenblatt DJ, Woo E, Franke K, Pfeifer JH, Smith TW: Single-and multiple-dose pharmacokinetics of oral quinidine sulfate and gluconate. American Journal of Cardiology 41:770-777, 1978.
- 76. Greenblatt DJ, Shader RI, Weinberger DR, Allen MD, MacLaughlin DS: Effect of a cocktail on diazepam absorption. <a href="Psychopharmacology">Psychopharmacology</a> 57:199-203, 1978.
- 77. Greenblatt DJ, Franke K, Huffman DH: Impairment of antipyrine clearance in humans by propranolol. <u>Circulation</u> 57:1161-1164, 1978.
- 78. Greenblatt DJ, Allen MD: Intramuscular injection-site complications.

  <u>Journal of the American Medical Association</u> 240:542-544, 1978.
- 79. Greenblatt DJ, Shader RI, Franke K, Harmatz JS: Pharmacokinetics of chlordiazepoxide and metabolites following single and multiple oral doses. International Journal of Clinical Pharmacology and Biopharmacy 16:486-493, 1978.
- 80. Lloyd BL, Greenblatt DJ, Allen MD, Harmatz JS, Smith TW: Pharmacokinetics and bioavailability of digoxin capsules, solution,

- and tablets after single and multiple doses. American Journal of Cardiology 42:129-146, 1978.
- 81. Greenblatt DJ, Allen MD: Toxicity of nitrazepam in the elderly: a report from the Boston Collaborative Drug Surveillance Program. British Journal of Clinical Pharmacology 5:407-413, 1978.
- 82. Ochs HR, Greenblatt DJ, Woo E, Franke K, Smith TW: Effect of propranolol on pharmacokinetics and acute electrocardiographic changes following intravenous quinidine in humans. <a href="Pharmacology">Pharmacology</a> 17:301-306, 1978.
- 83. Greenblatt DJ, Shader RI, MacLeod SM, Sellers EM, Franke K, Giles HG:
  Absorption of oral and intramuscular chlordiazepoxide. <u>European</u>
  Journal of Clinical Pharmacology 13:267-274, 1978.
- 84. Ochs HR, Greenblatt DJ, Dengler JH: Absorption of oral tetracycline in patients with Billroth-II gastrectomy. <u>Journal of Pharmacokinetics</u> and Biopharmaceutics 6:295-303, 1978.
- 85. Ochs HR, Greenblatt DJ, Bodem G, Harmatz JS: Dose-independent pharmacokinetics of digoxin in humans. <u>American Heart Journal</u> 97:507-511, 1978.
- 86. Greenblatt DJ, Woo E, Allen MD, Orsulak PJ, Shader RI: Rapid recovery from massive diazepam overdose. <u>Journal of the American Medical</u> Association 240:1872-1874, 1978.
- 87. Greenblatt DJ, Shader RI, MacLeod SM, Sellers EM: Clinical pharmacokinetics of chlordiazepoxide. Clinical Pharmacokinetics 3:381-394, 1978.
- 88. Sokol GH, Greenblatt DJ, Lloyd BL, Georgotas A, Allen MD, Harmatz JS, Smith TW, Shader RI: Effect of abdominal radiation therapy on drug absorption in humans. <u>Journal of Clinical Pharmacology</u> 18:388-396, 1978.
- 89. Ochs HR, Greenblatt DJ, Woo E, Smith TW: Reduced quinidine clearance in elderly persons. American Journal of Cardiology 42:481-485, 1978.
- 90. Greenblatt DJ, Franke K, Shader RI: Analysis of lorazepam and its glucuronide metabolite by electron-capture gas-liquid chromatography: use in pharmacokinetic studies of lorazepam. <u>Journal of Chromatog-raphy</u> 146: 311-320, 1978.
- 91. Shader RI, Georgotas A, Greenblatt DJ, Harmatz JS, Allen MD: Impaired absorption of desmethyldiazepam from clorazepate by magnesium aluminum hydroxide. Clinical Pharmacology and Therapeutics 24:308-315, 1978.
- 92. Woo E, Greenblatt DJ, Ochs HR: Short- and long-acting quinidine preparations: clinical implications of pharmacokinetic differences. Angiology 29:243-250, 1978.
- 93. MacLeod SM, Sellers EM, Giles HG, Billings BJ, Martin PR, Greenblatt DJ, Marshman JA. Interaction of disulfiram with benzodiazepines. Clinical Pharmacology and Therapeutics 24:583-589, 1978.
- 94. Sellers EM, Greenblatt DJ, Zilm DH, Degani N: Decline in chlordiazepoxide plasma levels during fixed-dose therapy of alcohol withdrawal. British Journal of Clinical Pharmacology 6:370-372, 1978.
- 95. Greenblatt DJ, Shader RI: Pharmacokinetic understanding of antianxiety drug therapy. Southern Medical Journal 71(Suppl 2): 2-9, 1978.

- 96. Greenblatt DJ, Shader RI: Dependence, tolerance, and addiction to benzodiazepines: clinical and pharmacokinetic considerations. <a href="Drug">Drug</a> Metabolism Reviews 8:13-28, 1978.
- 97. Greenblatt DJ: Simultaneous gas chromatographic analysis for diazepam and its major metabolite, desmethyldiazepam, with use of double internal standardization. Clinical Chemistry 24:1838-1841, 1978.
- 98. Greenblatt DJ, Allen MD, MacLaughlin DS, Harmatz JS, Shader RI:
  Diazepam absorption: effect of antacids and food. Clinical
  Pharmacology and Therapeutics 24:600-609, 1978.
- 99. MacLeod SM, Sellers EM, Giles HG, Billings BJ, Martin PR, Greenblatt DJ, Marshman JA: The interaction of disulfiram with benzodiazepines. Clinical Pharmacology and Therapeutics 24:583-589, 1978.
- 100. Stanski DR, Greenblatt DJ, Lowenstein E: Kinetics of intravenous and intramuscular morphine. Clinical Pharmacology and Therapeutics 24:52-59, 1978.
- 101. Greenblatt DJ, Shader RI: Prazepam and lorazepam, two new benzodiazepines. New England Journal of Medicine 299:1342-1344, 1978.
- 102. Mudge GH, Lloyd BL, Greenblatt DJ, Smith TW: Inotropic and toxic effects of a polar cardiac glycoside derivative in the dog. Circulation Research 43:847-854, 1978.
- 103. Greenblatt DJ, Allen MD, Harmatz JS, Noel BJ, Shader RI: Correlates of outcome following acute glutethimide overdosage. <u>Journal of Forensic</u> Sciences 24:76-86, 1979.
- 104. Greenblatt DJ, Shader RI, Franke K, MacLaughlin DS, Harmatz JS, Allen MD, Werner A, Woo E: Pharmacokinetics and bioavailability of intravenous, intramuscular and oral lorazepam in humans. <u>Journal of Pharmaceutical Sciences</u> 68:57-63, 1979.
- 105. Greenblatt DJ: Reduced serum alhumin concentration in the elderly: a report from the Boston Collaborative Drug Surveillance Program.

  Journal of the American Geriatrics Society 27:20-22, 1979.
- 106. Miller RR, Porter J, Greenblatt DJ: Clinical importance of the interaction of phenytoin and isoniazid: a report from the Boston Drug Surveillance Program. Chest 75:356-358, 1979.
- 107. Greenblatt DJ: Predicting steady-state serum concentrations of drugs. Annual Review of Pharmacology and Toxicology 19:347-356, 1979.
- 108. Woo E, Greenblatt DJ: Pharmacokinetic and clinical implications of quinidine protein binding. <u>Journal of Pharmaceutical Sciences</u> 68:466-470, 1979.
- 109. Woo E, Greenblatt DJ: Massive benzodiazepine requirements during acute alcohol withdrawal: a clinical and pharmacokinetic study. American Journal of Psychiatry 136:821-823, 1979.
- 110. Greenblatt DJ, Allen MD, MacLaughlin DS, Huffman DH, Harmatz JS, Shader RI: Single- and multiple-dose kinetics of oral lorazepam in humans: the predictability of accumulation. <u>Journal of</u> Pharmacokinetics and Biopharmaceutics 7:159-179, 1979.

- 111. Lowenthal IS, Parker LM, Greenblatt DJ, Brown BL, Samy TSA:
  Pharmacokinetic analysis of neocarzinostatin in normal and tumorbearing rodents. Cancer Research 39:1547-1551, 1979.
- 112. Greenblatt DJ, Allen MD, Locniskar A, Harmatz JS, Shader RI: Lorazepam kinetics in the elderly. Clinical Pharmacology and Therapeutics 26:103-113, 1979.
- 113. Pfeifer HJ, Greenblatt DJ, Friedman P: Effect of three antibiotics on theophylline kinetics. Clinical Pharmacology and Therapeutics 26:36-40, 1979.
- 114. Sellers EM, Greenblatt DJ, Giles HG, Naranjo CA, Kaplan H, MacLeod SM: Chlordiazepoxide and oxazepam disposition in cirrhosis. Clinical Pharmacology and Therapeutics 26:240-246, 1979.
- 115. Allen MD, Greenblatt DJ, Harmatz JS, Shader RI: Single-dose kinetics of prazepam, a precursor of desmethyldiazepam. <u>Journal of Clinical</u> Pharmacology 19:445-450, 1979.
- 116. Greenblatt DJ, Locniskar A: Spectrophotometric assay of antipyrine in plasma: a reevaluation. <u>International Journal of Clinical</u> Pharmacology and Biopharmacy 17:401-404, 1979.
- 117. Ochs HR, Grube E, Greenblatt DJ, Woo E, Bodem G: Intravenous quinidine: pharmacokinetic properties and effects on left ventricular performance in humans. American Heart Journal 99:468-475, 1980.
- 118. Greenblatt DJ, Allen MD, Harmatz JS, Noel BJ, Shader RI: Overdosage with pentobarbital and secobarbital: assessment of factors related to outcome. Journal of Clinical Pharmacology 19:758-768, 1979.
- 119. Allen MD, Greenblatt DJ, Noel BJ: Self-poisoning with over-the-counter hypnotics. <u>Clinical Toxicology</u> 15:151-158, 1979.
- 120. Ochs HR, Greenblatt DJ, Allen MD, Harmatz JS, Shader RI, Bodem G: Effect of age and Billroth gastrectomy on absorption of desmethyl-diazepam from clorazepate. Clinical Pharmacology and Therapeutics 26:449-456, 1979.
- 121. Greenblatt DJ, Allen MD, Harmatz JS, Shader RI: Diazepam disposition determinants. Clinical Pharmacology and Therapeutics 27:301-312, 1980.
- 122. Ochs HR, Greenblatt DJ, Harmatz JS, Bodem G: Serum digoxin concentrations and subjective manifestations of toxicity. Pharmacology 20:149-154, 1980.
- 123. Greenblatt DJ, Shader RI, Harmatz JS, Georgotas A: Self-rated sedation and plasma concentrations of desmethyldiazepam following single doses of clorazepate. Psychopharmacology 66:289-290, 1979.
- 124. Ochs HR, Greenblatt DJ, Lloyd BL, Woo E, Sonntag M, Smith TW: Entry of quinidine into cerebrospinal fluid. American Heart Journal 100:341-346, 1980.
- 125. Allen MD, Greenblatt DJ, Arnold JD: Single and multiple dose kinetics of estazolam, a triazolo benzodiazepine. <u>Psychopharmacology</u> 66:267-274, 1979.
- 126. Winokur A, Rickels K, Greenblatt DJ, Snyder PJ, Schatz NJ: Withdrawal reaction from chronic, low-dose diazepam administration: a double-

- blind placebo-controlled case study. Archives of General Psychiatry 37:101-105, 1980.
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